OCT - 3 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS K012986

in Accordance with SMDA of 1990

BIPOLAR IRRIGATION FORCEPS

August 21, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Lisa M. Millington, Regulatory Associate
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TRADE NAME: Bipolar Irrigation Forceps

COMMON NAME: Jet Irrigation Forceps

DEVICE CLASS: Class II

PRODUCT CODE: 79 GEI
CLASSIFICATION: 878.4400 – Electrosurgical Cutting & Coagulation Device & Accessories

REVIEW PANEL: General & Plastic Surgery

INTENDED USE

Aesculap's Bipolar Irrigation Forceps are designed to be used with Aesculap's currentJet Irrigation System (#K971310) and Bipolar Coagulator (#K952524). The Bipolar Irrigation Forceps are intended for use in electrosurgery for coagulation and irrigation of selected tissue.

DEVICE DESCRIPTION

The bipolar irrigation forceps (GK842R, GK845R, and GK848R) are a "Bayonet" style forceps, similar to Aesculap's currently marketed bipolar irrigation forceps (#K971310). The irrigation channel runs inside the right-hand prong, with an outlet 2.5mm above the tip of the forceps. The new bipolar irrigation forceps are available in lengths ranging from 180mm – 230mm with a tip size of 1.3mm.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new bipolar irrigation forceps conform to applicable ASTM and ISO standards. The bipolar irrigation forceps do meet the requirements of IEC 601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment).

SUBSTANTIAL EQUIVALENCE

The new Bipolar Irrigation Forceps described in this premarket notification are substantially equivalent to those in Aesculap's current Bipolar Forceps product lines (subjected to K971310, K944955, and pre-amendment devices) with regard to intended use, fundamental scientific technology, design and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 2001

Ms. Lisa M. Millington
Regulatory Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K012986
Trade/Device Name: Jet Irrigation Forceps
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 21, 2001
Received: September 6, 2001

Dear Ms. Millington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker MP

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K012986

Device Name: Jet Irrigation Forceps

Indication for Use:

Aesculap's Bipolar Irrigation Forceps are designed to be used with Aesculap's current Jet Irrigation System (#K971310) and Bipolar Coagulator (#K952524). The Bipolar Irrigation Forceps are intended for use in electrosurgery for coagulation and irrigation of selected tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012986

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)